

invention typically yield powders with bulk densities less than 0.1 g/cm^3 and often less than 0.05 g/cm^3 . It will be appreciated that providing powders having bulk densities an order of a magnitude less than conventional DPI formulations allows for much lower doses of the selected bioactive agent to be filled into a unit dose container or metered via reservoir-based DPIs. The ability to effectively meter small quantities is of particular importance for low dose steroid, long acting bronchodilators and new protein or peptide medicaments proposed for DPI delivery. Moreover, the ability to effectively deliver particulates without associated carrier particles simplifies product formulation, filling and reduces undesirable side effects.

IN THE CLAIMS

Please amend the claims as follows:

Please cancel claims 2 and 3

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4. The powder of claim 39 comprising a mean porosity of 0.5 – 80%.
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8. The powder of claim 39 further comprising a fine particle fraction of greater than 20% w/w.
9. The powder of claim 8 further comprising a fine particle fraction within 30-70% w/w.
10. The powder of claim 39 wherein the bulk density is less than 0.1 g/cm^3 .
11. The powder of claim 39 wherein the bulk density is less than 0.05 g/cm^3 .
12. The powder of claim 39 wherein said particulate microstructures comprises hollow porous microspheres.

13. The microspheres of claim 12 further comprising a shell thickness between 0.1 – 0.5 μm .

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amc

14. The powder of claim 39 wherein the mean aerodynamic diameter of said particulate microstructures is between 0.5 μm and 5 μm .

Please cancel claims 16 and 17

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18. The powder of claim 39 wherein said phospholipid is selected from the group consisting of dilauroylphosphatidylcholine, dioleoylphosphatidylcholine, dipalmitoylphosphatidylcholine, disteoylphosphatidylcholine, dibehenoylphosphatidylcholine, diarachidoylphosphatidylcholine and combinations thereof.

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20. The powder of claim 39 wherein said active agent is a bioactive agent.

21. The powder of claim 20 wherein said bioactive agent is selected from the group consisting of antiallergics, bronchodilators, pulmonary lung surfactants, analgesics, antibiotics, antiinfectives, leukotriene inhibitors or antagonists, antihistamines, antiinflammatories, antineoplastics, anticholinergics, anesthetics, anti-tuberculars, imaging agents, cardiovascular agents, enzymes, steroids, DNA, RNA, viral vectors, antisense agents, proteins, peptides and combinations thereof.

22. The powder of claim 20 wherein the bioactive agent is selected from the group consisting of nicotine, fentanyl, morphine, lung surfactant, parathyroid hormone, leuprolide, interferon, goserelin, and growth hormones.

23. A powder composition of claim 39 wherein said particulate microstructure comprises a perforated microstructure.

Please cancel claims 24 - 38

Please add the following new claims:

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39. A powder composition comprising a plurality of particulate microstructures, said microstructures comprising an active agent, calcium and a phospholipid, wherein said microstructures comprise a geometric diameter of 1-30 microns, an aerodynamic diameter of less than 5 microns, and a bulk density of less than about 0.5 g/cm³.

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40. A powder composition comprising a plurality of particulate microstructures, said microstructures comprising calcium and a phospholipid.

41. The powder of claim 40 wherein said microstructures comprise a geometric diameter of 1-30 microns, an aerodynamic diameter of less than 5 microns, and a bulk density of less than about 0.5 g/cm³.

42. The powder of claim 41 wherein the geometric diameter is less than 10 microns.

43. The powder of claim 42 further comprising an active agent.

44. The powder of claim 42 wherein the geometric diameter is less than 5 microns.

45. The powder of claim 43 or claim 44 wherein the bulk density is less than 0.1 g/cm³.

46. The powder of claim 45 wherein the bulk density is less than 0.05 g/cm³.

47. The powder of claim 40 wherein said phospholipid is selected from the group consisting of dilauroylphosphatidylcholine, dioleoylphosphatidylcholine, dipalmitoylphosphatidylcholine, disteoylphosphatidylcholine, dibehenoylphosphatidylcholine, diarachidoylphosphatidylcholine and combinations thereof.

48. The powder of claim 47 wherein said phospholipid comprises a gel to liquid crystal transition temperature of greater than 40° C.

Sub C3
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49. The powder of claim 43 wherein said active agent is a bioactive agent selected from the group consisting of antiallergics, bronchodilators, pulmonary lung surfactants, analgesics, antibiotics, antiinfectives, leukotriene inhibitors or antagonists, antihistamines, antiinflammatories, antineoplastics, anticholinergics, anesthetics, anti-tuberculars, imaging agents, cardiovascular agents, enzymes, steroids, DNA, RNA, viral vectors, antisense agents, proteins, peptides and combinations thereof.

50. The powder of claim 49 wherein the bioactive agent is selected from the group consisting of nicotine, fentanyl, morphine, lung surfactant, parathyroid hormone, leuprolide, interferon, goserelin, and growth hormones.

51. The powder of claim 49 wherein the bioactive agent is an aminoglycoside antibiotic.